

## **Exhibit 1**

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE  
LITIGATION

MDL No. 1456

C.A. No.: 01-CV-12257-PBS

THIS DOCUMENT RELATES TO  
ALL CLASS ACTIONS

Judge Patti B. Saris

**WATSON'S SURREBUTTAL RELATING TO CLASS CERTIFICATION**

Plaintiffs accuse Watson Pharmaceuticals, Inc. (“Watson”) of filing a “sprawling” pleading. But it is Plaintiffs who have complicated issues before the Court by seeking, for the first time (in a pleading that is titled a “rebuttal” to a “response” to a “response” to an “opposition to class certification”)<sup>1</sup> to certify Pirelli Armstrong Tire Corporation Retiree Medical Benefits Trust (“Pirelli”) and United Food Commercial Workers Unions and Employers Midwest Health Fund (“UFCW”) as class representatives. Setting aside these two entities, the issues are simple:

- the Court should not certify class representatives based on reimbursements of Ferrlecit (the proposed subject drug for an early trial against Watson), because the proposed class representatives reimbursed payments for that drug only after the appropriate class period (if there is any appropriate class period); and
- the Court, at this time, should not certify class representatives as to Watson based on multi-source drugs, because a) multi-source drugs are excluded from liability for Class 3, and b) the Court has postponed consideration of multi-source drugs for Track Two Defendants until the Court can engage in orderly, deliberate, and consolidated consideration of class certification for the Track Two Defendants that sold multi-source drugs.

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<sup>1</sup> Plaintiffs' Rebuttal to Watson Pharmaceutical, Inc.'s Response to Class Plaintiffs' Response to Amgen's and Watson's Supplemental Opposition to Class Certification, filed Sept. 27, 2007 (Docket No. 4747) (Plaintiffs' “Rebuttal”).

The Court should therefore deny class certification as to Watson.

**I. The Court Cannot Certify Pirelli and UFCW as Class Representatives.**

As recently as last month (Docket No. 4609, filed Aug. 8, 2007), Plaintiffs sought certification of only Pipefitters Local 537 Trust Funds (“Pipefitters”) and Sheet Metal Workers National Fund (“Sheet Metal Workers”) as class representatives for Watson.<sup>2</sup>

The fact that Plaintiffs are now seeking certification for Pirelli and UFCW was made clear yesterday, September 27, 2007, when Plaintiffs filed their Rebuttal. Rebuttal, at 3 (“now that Plaintiffs are seeking nationwide classes . . . Plaintiffs seek to use these representatives”). Plaintiffs attached a summary exhibit that they claim demonstrates adequate reimbursements from Pirelli and UFCW for Watson’s drugs. Plaintiffs do so without attaching underlying data, long after any reasonable deadline for class certification motions, and without permitting Watson an adequate opportunity to respond.

Plaintiffs admit that, in their prior pleadings, they had only filed supporting allegations as to Pipefitters and Sheet Metal Workers. *See* Rebuttal, at 1 n.1. Now that they have decided to seek Court approval of Pirelli and UFCW, Plaintiffs file a brand-new “Exhibit B,” but many of the references in that Exhibit are subject to attack. For example, in that Exhibit, Plaintiffs provide citations to many multi-source drug reimbursements for two proposed Class 3 representatives, but multi-source drugs have been excluded from liability for Class 3. Also, a citation listed as INFeD was actually for

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<sup>2</sup> The pleading filed by Plaintiffs immediately prior to their Rebuttal relied only on data for Sheet Metal Workers in Section III of its argument; Plaintiffs had earlier moved for certification as to Sheet Metal Workers and Pipefitters.

a competitor's drug, Dexferrum, in at least one of the records cited by the Plaintiffs in a data reference chart recently provided to back up that exhibit.<sup>3</sup> See SMW 67323-28.

The difficulty of unraveling and responding to these last-minute filings demonstrates why Plaintiffs should not be permitted to seek class certification without having actually moved for class certification as to these entities, with appropriate declarations, data, and records submitted, and a scheduled, orderly progression of filings to ensure that all allegations relating to class certification are properly supported, and opponents have an opportunity to respond. The Court should not entertain Plaintiffs' belated request to certify Pirelli and UFCW for Watson or other Track Two Defendants.

## **II. Watson's Arguments about the Class Period for Ferrlecit Are Properly Before the Court.**

The Court correctly held on August 27, 2007, that a Class 1 representative would not be certified for Amgen because the proposed class representative made a copayment for Amgen's drug only after the relevant class period. Likewise, the Court should certify a class representative for Ferrlecit only if a proposed class representative made a reimbursement for Ferrlecit during the relevant class period. None did.

Plaintiffs argue, in their Rebuttal, that the Court can make no inquiry into the merits of the appropriate class period. To the contrary, this Court has correctly ruled that the Court should probe, at the class certification stage, whether a proposed class representative has typicality and standing. *In re Pharm. Indus. Average Wholesale Price*

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<sup>3</sup> Although the Sheet Metal Workers documents had been provided months ago, it was not practical to search for relevant J-Codes by examining each of hundreds of thousands of entries until we received from Plaintiffs – quite recently – a data reference chart with the Bates numbers of relevant records nationwide.

*Litig.*, 230 F.R.D. 61, 78-79 (D. Mass. 2005). For the reasons set forth in Watson's Response,<sup>4</sup> the class period as to Ferrlecit must end in December 2000. All the reimbursements for Ferrlecit by Sheet Metal Workers occur after that.<sup>5</sup>

Plaintiffs claim that the end stage renal disease ("ESRD") drugs described in the OIG report discussed in Watson's Response do not include Watson's drug. *See Rebuttal*, at 5 n.3. In fact, the OIG report specifically discussed iron dextran, which Watson markets under the tradename INFeD. Plaintiffs also argue that it was the Medicare Modernization Act ("MMA") that resulted in reimbursement rates being cut for drugs, with offsetting increases to dialysis reimbursements. Plaintiffs are correct. However, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, 114 Stat. 2763 (2000) recognized that cross-subsidization needed to be maintained for dialysis clinics. The MMA provisions and congressional and deposition testimony by Thomas Scully established that the amount of the cross-subsidization was appropriate for ESRD drugs, since reductions in ESRD drug reimbursements were required to be offset, dollar-for-dollar, by increases in dialysis service reimbursements.

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<sup>4</sup> Watson Pharmaceuticals, Inc.'s Response to Class Plaintiffs' Response to Amgen and Watson's Supplemental Opposition to Class Certification, filed Sept. 14, 2007 (Docket No. 4716)(“Response”).

<sup>5</sup> Even if the Court decides consider Pirelli, Plaintiffs get no further. There were reimbursements for Ferrlecit by Pirelli only after December 2000. There were no Pipefitters reimbursements for Ferrlecit at any time.

**III. Multi-source Drug Reimbursements Are Not Sufficient to Support Class Certification as to Ferrlecit.**

There can be no debate that the Court has determined that there is no liability, in this case, for multi-source drugs for Class 3. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F.Supp. 2d 20, 39 (D. Mass. 2007). Because Plaintiffs have no Class 1 representative for Ferrlecit, as they have admitted, the relevant discussion, for now, is whether there is a Class 2 representative as to Watson for Ferrlecit based on reimbursements of multi-source drugs and, if so, whether the Court should now rule on the adequacy and typicality of those representatives as to Ferrlecit.

Watson will not repeat the reasons, set forth in its Response (at 5, 9-11), that the Court should not consider, at this time, class certification for any Track Two Defendant based on multi-source drug reimbursements. Plaintiffs maintain, at footnote 6 of their Rebuttal (citation omitted), that all they have to show is that class representatives “made co-insurance payments (at least in part) under Medicare Part B based on AWP.” Plaintiffs omit a critical step. Plaintiffs must establish that the class representatives made Medicare copayments for a subject drug based on AWP. Plaintiffs cannot do so for Watson’s drugs, because Watson’s generic multi-source drugs at issue were off the market at the time of the reimbursements.<sup>6</sup>

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<sup>6</sup> Plaintiffs state that Jeffrey Johnson did not review the Sheet Metal Workers claims data. Rebuttal, at 6. However, as discussed in the Declarations attached to Watson Pharmaceuticals’ Individual Memorandum in Opposition to Class Certification, filed June 15, 2006 (Docket No. 2810), Mr. Johnson reviewed a chart prepared by Watson’s counsel that showed the dates of the administrations of generic multi-source drugs purportedly reimbursed by Sheet Metal Workers attributed by Plaintiffs to Watson. See Declaration of Jeffrey L. Johnson, ¶ 25; Declaration of Michelle L. Butler, ¶¶ 6-10 & Ex. B.

The Court has left open the question of whether it will require Watson to face an early trial on Ferrlecit (Transcript of Aug. 27, 2007 hearing, at 33). If the Court is prepared to certify class representatives for Ferrlecit based on multi-source drug reimbursements, rather than doing so prematurely, the Court should postpone its consideration of these issues by scheduling Watson's class certification and trial on Ferrlecit with class certification and trial for Watson on its multi-source drugs.

Respectfully submitted,

/s/ Douglas B. Farquhar  
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